

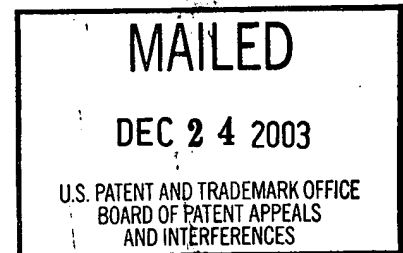
UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte JOHANNES C. VAN DER LAAN, and
CHRISTIAAN A. G. VAN EEKELEN

Appeal No. 2003-1239
Application No. 07/565,673

ON BRIEF



Before, SCHEINER, ADAMS, and GREEN, Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

VACATUR and REMAND TO THE EXAMINER

On consideration of the record we find this case is not in condition for a decision on appeal. For the reasons that follow, we vacate¹ the pending rejections and remand the application to the examiner to consider the following issues and to take appropriate action.

¹ Lest there be any misunderstanding, the term "vacate" in this context means to set aside or to void. When the Board vacates an examiner's rejection, the rejection is set aside and no longer exists.

Claims 41-55 are pending in the application. Claims 41 and 54 are illustrative of the subject matter on appeal and are reproduced below:

41. A method for the production of a mutant high alkaline protease, said method comprising the steps of:
- a) obtaining a non-reverting mutant alkalophilic *Bacillus* host incapable of producing a wild-type high alkaline protease, wherein said mutant alkalophilic *Bacillus* host comprises a chromosomal deletion of the gene encoding the wild-type alkaline protease and an integration cassette comprising a gene encoding a mutant high alkaline protease; and
 - b) growing said mutant alkalophilic *Bacillus* host under conditions whereby said mutant high alkaline protease is expressed.
54. A method for the production of a mutant high alkaline protease, said method comprising the steps of:
- a) obtaining an alkalophilic *Bacillus* host selected from the group consisting of *Bacillus novo* species PB92 and its derivatives wherein said derivatives retain the characteristics of *Bacillus novo* species PB92 and said alkalophilic *Bacillus* host is incapable of producing a wild-type high alkaline protease, and comprises a chromosomal deletion of the gene encoding the wild-type high alkaline protease;
 - b) transforming said alkalophilic *Bacillus* host with an integration cassette comprising a gene encoding a mutant high alkaline protease, wherein said gene encoding the mutant high alkaline protease comprises a replacement of at least one amino acid residue in the nucleotide sequence encoding the wild type protease of *Bacillus novo* species PB92 or derivative thereof to obtain a non-reverting mutant alkalophilic strain; and
 - c) growing said mutant alkalophilic *Bacillus* host under conditions whereby said mutant high alkaline protease is expressed.

The examiner offers no prior art to support the rejections of record.

GROUND OF REJECTION

Claims 41-47 stand rejected under 35 U.S.C. § 112, second paragraph, as indefinite in the recitation of the phrase "mutant high alkaline protease."

Claims 54 and 55 stand rejected under 35 U.S.C. § 112, second paragraph, as indefinite in the recitation of the phrase "Bacillus novo species PB92 and its derivatives."

Claims 41-55 stand rejected under 35 U.S.C. § 112, first paragraph, as the specification that fails to adequately describe the claimed invention.

Claims 41-47, 54 and 55 stand rejected under 35 U.S.C. § 112, first paragraph, as being based on an insufficient disclosure to enable the claimed invention.

For the following reasons, we vacate the pending rejections and remand the application to the examiner for further consideration.

DISCUSSION

I. What is a "mutant high alkaline protease"?

The examiner does not address this question. Instead, the examiner focuses our attention on amino acid or DNA sequence information, arguing that since appellants' specification does not define the specific amino acid residue or nucleic acid that appellants intend to modify "the metes and bounds of the claimed invention cannot be determined...." See Answer, page 4. It is unclear, however, why the examiner limited this rejection to claims 41-47. Claim 54, for example, requires the "replacement of at least one amino acid residue in the

nucleotide sequence encoding the wild type protease of *Bacillus novo*....” The exact amino acid residue is not identified in the claim. Thus it would appear that at least claim 54 would suffer from the same defect as claims 41-47.

In addition, as we understand the examiner’s arguments, it appears that the examiner is concerned that the specification does not provide an enabling description of the claimed invention. See e.g., Answer, page 4,

it is unclear what specific amino acid residues are to be mutated in the “mutant high alkaline protease” so as to make or produce a mutant that has different properties compared to the wild-type high alkaline protease. ... While the specification provides a general description of how to obtain a mutant protease by genetically manipulating the DNA sequence encoding the wild-type protease, the specific nucleotides which must be mutated in order to make a DNA sequence that encodes a mutant protease with different properties have not been defined in the specification.

We note that the examiner does not question the intended scope, or breadth, of the phrase “mutant high alkaline protease,” which is a proper question under the second paragraph of 35 U.S.C. § 112.² Instead the examiner focuses entirely upon the failure of the specification to provide an enabling description of the claimed invention. In our opinion, this issue properly falls within the requirements of the first paragraph of 35 U.S.C. § 112, not the second paragraph. We remind the examiner that the enablement provision of 35 U.S.C. § 112, first paragraph, requires that a patent application adequately disclose the claimed invention so as to enable a person skilled in the art to practice the

² The legal standard for indefiniteness under 35 U.S.C § 112, second paragraph, is whether a claim reasonable apprises those of skill in the art of its scope. See, Amgen Inc. v. Chugai Pharmaceutical Co., Ltd. 927 F.2d 1200, 1217, 18 USPQ2d 1016, 1030 (Fed. Cir. 1991).

invention at the time the application was filed without undue experimentation.

Enzo Biochem, Inc. v. Calgene, Inc., 188 F.3d 1362, 1371-72, 52 USPQ2d 1129, 1136 (Fed. Cir. 1999). Accordingly, we vacate the outstanding rejection and remand the application to the examiner to reconsider the record in view of the relevant statutory provision.

Notwithstanding the foregoing inconsistencies, this record does not establish that the examiner and appellants have explored the full scope of the phrase "mutant high alkaline protease." In responding to the examiner's rejection, appellants direct our attention to page 10, lines 11-20 of the specification, which according to appellants defines high alkaline proteases "as proteases produced by alkalophilic Bacillus strains." Brief, page 8. According to appellants' specification "alkalophilic bacilli are defined as Bacillus strains that grow under alkaline conditions ... [and] are described in, for example, U.S. Patent Nos. 3,723,250, Re. 30,602 and 4,480,037." Appellants' also direct our attention to page 13 of their specification where mutations to the high alkaline proteases are described.

Of particular interest, however, is appellants' disclosure that "[t]he polypeptide of interest [the high alkaline protease] may be any polypeptide for which expression is desired and may be either homologous (derived from the host cell) or heterologous (derived from a foreign source or a synthetic DNA sequence). Preferably the polypeptide is a mutant high alkaline protease, most preferably the mutant protease is one described in EP-A-0328229 and

WO[]89/06279....” Specification, bridging paragraph, pages 12-13.

As we understand appellants’ disclosure, the mutant high alkaline protease – the polypeptide – can be obtained from a source other than the from the host cell. To clarify, according to claim 41, the host cell is an alkalophilic Bacillus host, as appellants point out, the high alkaline protease is a protease derived from an alkalophilic Bacillus strain. As discussed above, the specification discloses that various strains of alkalophilic Bacillus are known in the art. For illustrative purposes, assume we have two alkalophilic Bacillus strains: strain A and strain B. Strain B will be the host as defined in claim 41. Strain A is the source of the mutant high alkaline protease. Note that no modification (as in genetic manipulation, amino acid replacement, etc.) is made to the protease derived from strain A. The protease of strain A is simply heterologous to the wild-type protease of strain B. Using the language of appellants’ specification, the mutant high alkaline protease of strain A is “derived from a foreign source” relative to the host strain B. Simply stated claim 41 reads on substituting the high alkaline protease of a first alkalophilic Bacillus strain, with the high alkaline protease from a second alkalophilic Bacillus strain. The record presented for our review, does not appear to have considered this interpretation of the claimed invention. Accordingly, upon return of the application to the examiner, we encourage the examiner to take a step back and reconsider the full scope of the claimed invention. In doing so we encourage the

examiner to consider page 13, lines 1-3 of appellants' specification, "most preferably the mutant protease is one described in EP-A-0328229 and WO[]89/06279...." Prior to any further prosecution on the merits, we encourage the examiner to consider the effect, if any, that these references may have on the claimed invention.

II. Is the phrase "Bacillus novo species PB92 or derivative thereof" indefinite?

According to the examiner (Answer, page 5), "it is unclear whether the claimed Bacillus novo species PB92 derivatives [of claims 54 and 55] have the same properties or characteristics of the parent Bacillus novo species PB92 or has properties or characteristics that completely differ from the parent Bacillus novo species PB92." The examiner finds (id.), "[t]he claims do not explicitly state that the claimed derivatives do or do not have the properties or characteristics of the parent Bacillus novo species PB92."

We are unable to follow the examiner's reasoning on this issue. As we understand claim 54, from which claim 55 depends, the derivatives "retain the characteristics of Bacillus novo species PB92." Thus, contrary to the examiner's position, the claims do expressly state that the claimed derivatives have the characteristics of the parent Bacillus novo species PB92.

Since the examiner has failed to clearly articulate the basis for the outstanding rejection we vacate the rejection and remand the application to the examiner for further consideration.

III. Written description:

After recognizing appellants' response to the written description rejection, the examiner restates a series of unsupported conclusions and finds (Answer, page 6), "[t]he inventors have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize the inventors were in possession of the claimed invention."

Conspicuous by its absence, is any statement by the examiner as to why, at a minimum, pages 3, 4, 10-13, 16, 23, 26, 27, 29 of appellants' specification are not sufficient to adequately describe the claimed invention as argued by appellants. See Brief, pages 11, 13, and 14. In our opinion, the examiner failed to adequately respond on this record to appellants' arguments. Accordingly, we vacate the pending rejection, in order to provide the examiner an opportunity to reconsider the issue of written description in light of appellants' arguments, appellants' specification and the prosecution history to date. If, after having the opportunity to fully consider the issue, the examiner believes that a rejection is necessary, we encourage the examiner to clearly articulate the basis for the rejection on the record. In making any such rejection, the examiner should exercise care to fully respond to appellants' arguments in favor of patentability and to clearly identify the factual evidence relied upon to support any such rejection.

IV. Enablement:

According to the examiner (Answer, pages 7-8),

[t]he amount of experimentation to practice the claimed invention is enormous and undue....

In view of the quantity of experimentation necessary, the limited working examples, the unpredictability of the art, the lack of sufficient guidance in the specification and the breadth of the claims, it would take an undue amount of experimentation for one skilled in the art to practice the claimed invention.

It is well settled that the examiner bears the initial burden of providing reasons why a supporting disclosure does not enable a claim. In re Marzocchi, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971). Furthermore, whether the disclosure is enabling, is a legal conclusion based on several underlying factual inquiries. To assist the fact finder in meeting his initial burden of setting forth a reasonable explanation as to why he believes the scope of the claimed invention is not adequately enabled by the description, our appellate reviewing court has outlined a number of factors that may be considered. See In re Wands, 858 F.2d 731, 735, 736-37, 8 USPQ2d 1400, 1402, 1404 (Fed. Cir. 1988), the factors to be considered in determining whether a claimed invention is enabled throughout its scope without undue experimentation include the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims. While these "factors are illustrative, not mandatory. What is relevant depends on the facts." Enzo

Biochem., Inc. v. Calgene, Inc., 188 F.3d 1362, 1371, 52 USPQ2d 1129, 1136 (Fed. Cir. 1999).

On this record, we find no fact-based analysis by the examiner. Instead, we find only the examiner's unsupported conclusions as to why the specification does not enable the claimed invention. We remind the examiner that nothing more than objective enablement is required, and therefore it is irrelevant whether this teaching is provided through broad terminology or illustrative examples. Marzocchi, 439 F.2d at 223, 169 USPQ at 369. In the absence of a fact-based statement of a rejection based upon the relevant legal standards, the examiner has not sustained his initial burden of establishing a prima facie case of non-enablement.

Furthermore, we find no discussion, or even recognition, by the examiner, of appellants' specific arguments that, at a minimum, direct attention to pages 10-15 of the specification. See e.g., Brief, pages 15-17. Accordingly, we vacate the pending rejection, in order to provide the examiner an opportunity to reconsider the issue of enablement in light of appellants' arguments, appellants' specification and the prosecution history to date. If, after having the opportunity to fully consider the issue, the examiner believes that a rejection is necessary, we encourage the examiner to clearly articulate the basis for the rejection on the record. In making any such rejection, the examiner should exercise care to fully respond to appellants' arguments in favor of patentability and to clearly identify the factual evidence relied upon to support any such rejection. In reconsidering

the issue of enablement, we recommend that the examiner review Enzo Biochem, Inc. v. Calgene, Inc., 188 F.3d 1362, 52 USPQ2d 11297 (Fed. Cir 1999). Therein, the court provided a model analysis of enablement issues and illustrates the type of fact finding which is needed before one is in a proper position to determine whether a given claim is enabled or non-enabled.

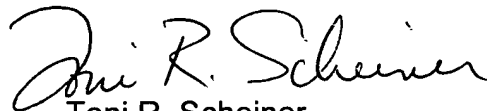
SUMMARY

For the foregoing reasons all outstanding rejections are vacated. The application is remanded to the examiner for further consideration.

FUTURE PROCEEDINGS

We are not authorizing a Supplemental Examiner's Answer under the provisions of 37 CFR § 1.193(b)(1). Any further communication from the examiner that contains a rejection of the claims should provide appellants with a full and fair opportunity to respond.

VACATED and REMANDED



Toni R. Scheiner
Administrative Patent Judge



Donald E. Adams
Administrative Patent Judge



Lora M. Green
Administrative Patent Judge

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